CERTIFICATION

I, the undersigned, am a professional translator, fully competent to translate from German into English, and I declare hereby that the attached English rendition of the PCT International Preliminary Examination Report dated Feb. 26, 2004, as issued an International Patent Application PCT/EP03/04087 is a genuine translation, accurate in every particular, to the best of my ability and knowledge.

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Date: Sept. 20, 2004

International Preliminary Examining Report of 26/02/2004

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1. This internal preliminary examining report is issued by the Office assigned therewith and is forwarded to the applicant in accordance with Article 36.

2. This report comprises all told 6 pages including the cover page.

Moreover. The report is accompanied by ATTACHMENTS; these are pages containing descriptions, claims and/or drawings which were altered and which are the basis of this report, and/or pages with amendments made before this authority (see Rule 70.16 and Section 607 of the Guidelines for PCT)

These enclosures comprise all told 4 pages.

I X Basis of the report

III X No Issue of Opinion as to Novelty, Inventive Step and Commercial Applicability

V X Reasoned opinion according to Rule 66.2a)ii) regarding novelty, inventive step and commercial applicability: documents and explanation in support thereof

I. Basis of the Report

1.This report was drawn up on the basis (replacement pages filed upon request by the Office according to Article 14 shall be considered within the scope of this report as "originally filed" and are attached as they do not contain any alterations (Rules 70.16 and 70.17)):

Specification, Pages:

1-22 original version

Claims, Nos.:

1-15 submitted on 11.11.2003 with the letter dated 06.11.2003

Drawings, pages:

1/6 –6/6 original version

III. No Issue of Opinion as to Novelty, Inventive Step and Commercial Applicability

The following parts of the present application were not examined as to whether the claimed invention is to be considered as novel, based on inventive step (not obvious) and commercially applicable:

X Claims No. 14,15.

Reason:

X No international Search Report was issued for the abovementioned claims No. 14, 15.

V. Reasoned opinion to according Art 35(2) regarding novelty, inventive step and commercial applicability: documents and explanation in support thereof

1. Opinion

Novelty (N)	Yes: Claims 1-13
Inventive step (IS)	Yes: Claims 1-13
Commercial applicability (CA)	Yes: Claims 1-13

2. Documents and Explanations

see accompanying page

INTERNATIONAL PRELIMINARY REPORT
ACCOMPANYING PAGE

To point V

Reasoned opinion to according Art 35(2) regarding novelty, inventive step and commercial applicability: documents and explanation in support thereof

(1) Reference is made to the following documents:

D1: US-A-5 460 610 (DON MICHAEL T. ANTHONY) October 24, 1995 (1995-10-24)
D2: US-A-4 445 892 (LOEB MARVIN P. ET AL) May 1, 1984 (84-05-01)

(2) Document D1 is viewed as the closest prior art for the subject matter of claim 1. It discloses a device for minimally invasive intravascular aortic valve extraction according to the introductory part of claim 1.

Therefore, the subject matter of claim 1 differs from this prior art device by the features of the characterizing part of claim 1.

Thus the subject matter of claim 1 is new (Article 33(2) PCT).

The object to be solved with the present invention can therefore be viewed to provide a simplified possible manner to introduce additional catheters into the working area between the dilation units.

The solution proposed in claim 1 of the present

application is based on inventive step (Article 33(3)PCT) for the following reasons:

All the documents in the found prior art indicate the possibility of integrating additional lumen in the perfusion catheter which have an opening between the dilation units. None of the documents shows or makes obvious the possibility to provide guide channels in the dilation units. Due to which the design of the perfusion catheter itself is simpler and it can be constructed slimmer in diameter because additional lumen are obviated.

Claims 1 to 13 are dependent on claim 1 and therefore also fulfill the requirements of PCT with regard to novelty and inventive step.

(3) The invented device can be produced industrially; the criterion of commercial applicability is fulfilled (Art. 33(4)PCT).

(4) Further notes

The description is not in harmony with the claims as prescribed in Rule 5.1 a)iii) PCT:

- The preferred embodiment described on page 6, in the middle, and on page 9, in the middle, is not part of the present claims. This contradiction between the claims and the description leads to doubts as to the subject matter of the sought protection and therefore the claims are not clear (Article 6 PCT).

- Passage p. 6, l. 4-5 does not comply with Rule 39 (1) iv PCT.

- In contradiction to the requirements of Rule 5.1 a)ii)PCT, the description does not mention the pertinent prior art documents disclosed in D1 and D2 nor the documents themselves.

What Is Claimed Is:

1. A device for minimally invasive, intravascular aortic valve extraction inside the aorta,
wherein a perfusion catheter (1) is provided having at least one perfusion channel designed as a hollow channel and at least two dilation units 2,3 disposed at a distance from each other at the distal catheter region in the longitudinal extension of said catheter, both said dilation units being projected through by said perfusion catheter (1) and forming in an inflated state an at least practically fluid-tight occlusion with the aortic wall (A), of which said dilation units (2,3) at least said dilation unit (2) disposed on the proximal side is provided with at least one passage through which at least one auxiliary catheter can be introduced for aortic valve ablation in a fluid-tight manner and/or said perfusion catheter (1) is provided with a working channel (8) which is provided with an outlet opening (9) in the region between said two dilation units and through which at least one auxiliary catheter can be introduced aortic valve ablation.

2. The device according to claim 1,
wherein said dilation units (2,3) are balloon elements which are inflatable with a medium and are disposed at a distance of at least 1 cm from each other in the longitudinal extension of said catheter.

3. The device according to claim 1 or 2,
wherein said at least one passage is provided at the circumferential edge of said dilation unit (2) disposed on the proximal side, when said dilation unit (2) is in an inflated state, said at least one passage being bound sickle-like by said circumferential edge of said dilation unit (2) and the remaining part by said aortic wall.

4. The device according to one of the claims 1 to 3,
wherein said at least one passage projects through said dilation unit (2) disposed on the proximal side and is completely surrounded by said dilation unit (2).

5. The device according to one of the claims 1 to 4,
wherein said at least one passage is designed in the manner of a ring-shaped sluice (R) which is surrounded, on the one hand, by said perfusion catheter (1) and, on the other hand, by said dilation unit (2) disposed on the proximal side.

6. The device according to one of the claims 1 to 5,
wherein at least said dilation unit (2) disposed on the proximal side is disposed in a rotary moveable manner about said perfusion catheter (1).

7. The device according to one of the claims 1 to 6,
wherein inside said perfusion channel of said perfusion catheter (1) a pump device is provided and
wherein on the proximal side to said dilation unit (2) disposed on the distal side an opening (6) is provided through which a blood flow enters said perfusion catheter (1) and exits said perfusion catheter (1) on the proximal side at an opening (7).

8. The device according to one of the claims 1 to 7,
wherein said dilation unit (2) disposed on the proximal side is provided with two passages for fluid-tight introduction of a coronary perfusion catheter (C) provided at the circumferential edge each with a dilatable cuff (C'),
wherein at least three further passages (A_1,A_2,I,O) are provided in said dilation unit (2) disposed on the proximal side, of said three further passages (A_1,A_2,I,O) one serves for introducing an ablation instrument (10), another for introducing an observation and/or rinsing unit and a third one for introducing a drainage.

9. The device according to one of the claims 1 to 8,
wherein said at least one passage (A_1,A_2) is provided with a sluice mechanism by means of which said passage is sealed fluid-tight in an inflated state without the provision of an auxiliary catheter.

10. The device according to claim 9,
wherein said passage is surrounded by an elastic channel wall whose opposite channel wall regions lie close together fluid-tight in an inflated state.

11. The device according to one of the claims 1 to 10,
wherein said dilation units (2,3) are connected each to a supply line through which a medium is introduced for inflating.

12. The device according to one of the claims 1 to 11,
wherein said dilation units (2,3) are designed as suction elements which can be inflated with a medium and which have a bell-shaped form into whose semi-open bell interior (13) a suction line (14) runs.

13. The device according to claim 12,
wherein said bell-shaped form of said suction elements is made of an elastic material which is designed double-walled and encloses an inflatable volume (12).

For USA

14. A method for minimal-invasive, intravascular aortic valve extraction inside the human aorta characterized by the following process steps:
- introduction of a coronary artery perfusion catheter into the right coronary artery and another perfusion catheter into the left coronary artery and inflation of a cuff provided at each coronary artery perfusion catheter respectively, with a blood flow being ensured through said coronary artery perfusion catheters into the coronary arteries,
- intravascular introduction of a perfusion catheter which is provided near its distal end with two dilation units disposed at a distance from each other,
- positioning of said perfusion catheter inside the aorta in such a manner that the aortic valve is surrounded on both sides inside the aorta by said dilation units,
- inflation of both said dilation units in such a manner that said dilation units lie close to the aortic wall in a fluid-tight manner,

- emptying the blood volume inside said two dilation units by means of introducing at least one auxiliary catheter projecting through said dilation unit disposed on the proximal side to create a working volume, and
- separation of the aortic valve inside said working volume by means of introducing at least one separation instrument projecting through said dilation unit disposed on the proximal side.

15. The method according to claim 14,
wherein said separation of the aortic valve is conducted under optical observation by means of an optic catheter whose distal end projects into said working volume.